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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,476	10/05/2006	Masao Sudoh	Q94153	2354

65565 7590 04/15/2008

SUGHRUE-265550
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EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,476	SUDOH ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3 pages / 04/03/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's reply filed on December 18, 2007.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-13) in the reply filed on December 18, 2007 is acknowledged.

Status of Claims

Amendment of claims 2 and 10, and cancellation of claim 16 is acknowledged.

Claims 1-15 are currently pending and are the subject of this office action.

Claims 14-15 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 18, 2007.

Claims 1-13 are presently under examination.

Priority

The present application is a 371 of PCT/JP04/14896 filed on 10/01/2004, and claims priority to foreign application: JAPAN 2003-345125.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toda et. al. (US 6,608,221) in view of Black (US 6,043,223) or Sakanaka (US 2003/0104079).

Claims 1-2, 5-7 and 13 recite an infusion preparation comprising (2R)-2-propyloctanoic acid or a salt thereof and a basic metal ion, which has a pH of about 5.0 to about 9.0 (claim 7).

For claims 1-2, 5-7 and 13, Toda et. al. teach a composition comprising (2R)-2-propylocatnoic acid (see title for example). Toda et. al. do not describe an infusion comprising (2R)-2-propyloctanoic acid. However, preparation of infusions of known drugs is a very well known procedure in the art. For example Black describes an infusion preparation of bradykinin that is dissolved in aqueous solution containing sodium hydroxide (basic metal ion) and phosphate buffered saline (PBS, pH ~ 6-8) solution (see column 5, lines 47-62). The statement in claim 13: "which is an agent for preventing and/or treating neurodegenerative diseases, nerve disorders or diseases in need of nerve regeneration", is considered an intended use and does not add any new limitation to the claim. Catalina Mktg. Int'l, Inc. V. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (fed. Cir. 2002). "The recitation of a new intended use for an old product does not make a claim to that old product patentable." In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Claim 3, recites the same limitation as claim 1, wherein the infusion, further comprises one or at least two selected from (i) electrolytes, (ii) saccharides, (iii) vitamins and (iv) protein aminoacids. For claim 3, Sakanaka further teaches an intravenous

infusion where the active compound is dissolved in an aqueous solution containing: sodium chloride (an electrolyte), phosphate buffer, glucose (a saccharide), liposome or fat emulsion (see paragraph [0235] on page 35).

Claims 4 and 10-11, recite the same limitations as claim 1, wherein the infusion comprises about 1 to about 5 equivalents of the basic metal ion used on 1 equivalent of (2R)-2-propyloctanoic acid. For claims 4, and 10-11, Black teaches an infusion of bradykinin (10-40 micrograms/mL) and 0.09% phosphate buffered saline solution (see column 5, fourth paragraph). This solution is equivalent to a ratio of basic metal ion (sodium) to bradykinin of 3 to 4 to 1.

Claims 8-9, recite the same limitations as claim 1, wherein the amount of (2R)-2-propyloctanoic acid is about 0.1 to about 20 mg per mL. These are standard concentrations for active substances delivered as infusions. See for example Black, column 5, fourth paragraph, were it says: "For intravenous administration, the concentration of bradykinin (active ingredient) is preferably between about 15 micrograms/mL to 50 mg/mL.

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to prepare an infusion of a known drug like (2R)-2-propyloctanoic acid, based on the teachings of the prior art on how to prepare those infusions, thus resulting in the practice of claims 1-13 with a reasonable expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, and 7-13 of copending Application No. 10/574,477. Although the conflicting claims are not identical, they are not patentably distinct from each other because: the instant claims are drawn to an infusion preparation comprising (2R)-2-propyloctanoic acid, or a salt thereof and a basic metal ion; while the copending claims are drawn to a medicament comprising (2R)-2-propyloctanoic acid, or a salt thereof and a basic metal ion.

At the time of the invention it would have been prima facie obvious for a person of ordinary skill in the art to start with the copending application teachings to get the instant applicant's infusion with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLS

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615